

Appl. No. 10/802,166
Atty. Docket No. 9184M
Amdt. dated 02/06/2009
Reply to Office Action of 08/06/2008
Customer No. 27752

REMARKS

Claim Status

Claims 1, 3, 4 and 7-25 are pending in the present application. No additional claims fee is believed to be due.

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

Rejection Under 35 USC § 112

Claim 4 has been rejected under USC § 112, second paragraph, as being indefinite for failing to point out and distinctly claims the subject matter which applicant regards as invention. The Office Action asserts that Claim 4 recites that the surfactant with an anionic functional group (hence anionic surfactant) is about 1% to about 50% of the total composition. However, Claim 1 limits the amount of surfactant to about 10% to about 50% thus requiring correction. Applicants have deleted Claim 4.

Claims 12 and 13 are rejected under USC § 112, second paragraph, as being indefinite for failing to point out and distinctly claims the subject matter which applicant regards as invention. Claims 12 and 13 recite “greater than about” wherein the Office Action has asserted that the limitation is either greater or the limitation is about. It further asserts that “Greater” provides a static fixed point while “about” provides a dynamic point. Therefore, it is unclear if the limitation is greater than X or about X. Applicants have further amended Claims 12 and 13 wherein the term “about” has been deleted.

New Claims 26 and 27 have been added to further define the present invention. Support for these claims is found in the claim set as filed, as well as the specification at page 4 line 31 to page 6, line 7 and at page 7 lines 1-26.

In light of the above remarks, it is requested that the Examiner reconsider and withdraw this rejection under 35 USC §112.

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Rejection Under 35 USC §102(b) Over WO 01/00151 (Gavin et al.)

Claims 1, 3, 4, 7 -13 and 18-25 have been rejected under 35 USC §102(b) as being anticipated. WO 01/00151 to Gavin et al (hereinafter “Gavin et al.”) as evidenced by the Wikipedia Zinc Oxide.

Gavin et al. discloses topical compositions for the treatment of microbial infections on the skin or scalp. Specifically, the composition of Gavin et al. includes from about 0.001% to about 10% by weight of the composition, of an anti-microbial active selected from the group consisting of polyvalent metal salts of pyrithione, from about 0.001% to about 10%, by weight of the composition, of a metal ion source selected from the group consisting of zinc salts, copper salts, silver salts, nickel salts, cadmium salts, mercury salts, bismuth salts and mixtures thereof and a topical carrier for the anti-microbial active and the metal salt.

The present invention, as currently amended, is directed to a personal care composition comprising from about 0.001% to about 5% of a zinc-containing layered material; from about 10% to about 50% of a surfactant including a surfactant with an anionic functional group; from about 0.01% to about 5% of a pyrithione or a polyvalent metal salt of a pyrithione; wherein the zinc-containing layered material has a relative zinc lability of greater than about 15%. Gavin et al. does not disclose or suggest a zinc-containing layered material having a relative zinc lability of greater than about 15%. The Office Action asserts that the disclosure of Gavin et al. discloses that the zinc salt can be zinc oxide. The Office Action further asserts that from Wikipedia, zinc oxide is shown to clearly have a layered crystal structure. Therefore, since zinc oxide is a zinc layered material it would inherently have the same relative zinc lability of greater than about 15%, to greater than about 20% and to greater than about 25% and thus meet the limitations of the instant claims 1, 12 and 13. Applicants respectfully traverse this rejection.

Applicants respectfully maintain that zinc oxide is not a zinc containing layered material (i.e. ZLM). All chemical structures have repeating units occurring in three dimensions. Thus, it can appear to those looking at any crystal structure, that there are

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repeating layers. However, in conventional structural chemistry, the term “layered structures” refers to structures in which only very weak forces hold layers together. Information concerning layered structures is provided at <http://wwwold.ill.fr/dif/3D-crystals/layers.html>, a copy of which is enclosed herein.

The classical example would be diamond and graphite, both solid carbon materials differing only in the three-dimensional arrangement of the atoms. While the diamond crystal lattice has repeating “layers,” the bond strength is equally strong in all three dimensions. The resulting material is one of the strongest materials in existence. By contrast, graphite has strong bonds in only two dimensions (the “layers”), with only weak bonds between the layers, resulting in a very soft material. Information concerning these distinctions provided at <http://www.bris.ac.uk/Depts/Chemistry/MOTM/diamond/diamond.htm>, a copy of which is enclosed.

Likewise, zinc oxide has three-dimensionally symmetric bonding strength, without functionally identifiable layers; however, looking at the crystal lattice, there are repeating units in three dimensions and thus one could focus on two of the dimensions and consider them “layers”. In contrast, in zinc containing layered materials, such as basic zinc carbonate, there are well-defined layers of a given chemical composition that have strong intra-layer bonds but are only held together between layers by “gallery ions,” weak ionic bonds.

This is further supported by the Applicants specification on page 5, lines 5-10, which states zinc-containing layered structures are those with crystal growth primarily occurring in two dimensions. It is conventional to describe layer structures as not only those in which all the *atoms* are incorporated in well-defined layers, but also those in which there are *ions or molecules* between the layers, called gallery ions (A.F. Wells “Structural Inorganic Chemistry” Clarendon Press, 1975). Zinc-containing layered materials (ZLM’s) may have zinc incorporated in the layers and/or be components of the gallery ions. Therefore, the specification is disclosing layer structures as not only those in which all the *atoms* are incorporated in well-defined layers, but also those in which there are *ions or molecules*

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between the layers. This is the differentiation between crystal structure (atomic level) vs. crystal habit (shape that physically observable crystals take).

Applicants further refute the Office Action's assertion that since zinc oxide is a zinc layered material it would inherently have the same relative zinc lability of greater than about 15%, to greater than about 20% and to greater than about 25% and thus meet the limitations of the instant claims 1, 12 and 13 based on data provided in the present application. Applicants direct attention to the specification at Page 30 line 33 to page 31 line 10, reproduced below:

-- Using this methodology, the below examples demonstrate a material (basic zinc carbonate) that has intrinsically high lability in an anionic surfactant system compared to one (ZnO) with low intrinsic lability.

	Relative Zinc Lability (%)	Relative Zinc Lability (%)	Lability Benefit
	In Water	In Simple Surfactant System ¹	
Zinc Oxide	86.3	1.5	NO
Basic zinc carbonate	100	37	YES

¹Simple surfactant system: 6% sodium lauryl sulfate --

Clearly this data demonstrates, per column 2, that basic zinc carbonate, which is a zinc-containing layered material, in an anionic surfactant system, provides a lability benefit by achieving a relative zinc lability of 37%. In contrast, zinc oxide, in the same anionic surfactant system, has no lability benefit and only achieves a relative zinc lability of 1.5%. Therefore, zinc oxide does not inherently have the same relative zinc lability of greater than about 15%, to greater than about 20% and to greater than about 25% and thus does not meet the limitations of the instant claims.

In short, Applicants maintain that personal care compositions comprising a zinc-containing layered material having a relative zinc lability of greater than about 15%, as

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instantly claimed, is neither disclosed nor suggested by Gavin et al. When one of ordinary skill in the art compares the composition of Gavin et al. to the instantly claimed invention, the compositions are not comprised of the exact same materials; namely Gavin et al. does not teach or suggest a zinc-containing layered material, such as basic zinc-carbonate or others and would not inherently have the exact same properties as the currently claimed product, namely a zinc containing layered material having a relative zinc lability of greater than about 15%.

In light of the above remarks, it is requested that the Examiner reconsider and withdraw this rejection under 35 USC §102(b).

Rejection Under 35 USC §102(b) Over US 5,227,156 (Wiese)

Claims 1, 3, 4, 7, 8-13, 20 and 21 have been rejected under 35 USC §102(b) as being anticipated. US 5,227,156 to Wiese (hereinafter “Wiese”) as evidenced by the Wikipedia Zinc Oxide.

Wiese discloses that the activity of a thiazolinone preservative, in an anti-dandruff shampoo containing pyrithione, is maintained by adding a stabilizer comprising a zinc compound. Specifically, Wiese discloses an aqueous anti-dandruff shampoo comprising up to about 40% of a surfactant, from about 0.1% to about 2% zinc pyrithione, from about 1 to about 30 ppm of a preservative selected from the group consisting of 5-chloro-2alkyl-4-isothiazolin-3-one, 2-alkyl-4-isothiazolin-3-one, wherein the alkyl is selected from the group consisting of methyl, ethyl, butyl, propyl and mixtures thereof, from about 0.001% to about 1% of a preservative stabilizer comprising a zinc compound selected from the group consisting of a zinc salt of an organic acid, a zinc salt of an inorganic acid, zinc oxide, zinc hydroxide, and mixtures thereof, and the balance comprising water.

The present invention, as currently amended, is directed to a personal care composition comprising from about 0.001% to about 5% of a zinc-containing layered material; from about 10% to about 50% of a surfactant including a surfactant with an anionic

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functional group; from about 0.01% to about 5% of a pyrithione or a polyvalent metal salt of a pyrithione; wherein the zinc-containing layered material has a relative zinc lability of greater than about 15%.

Wiese does not disclose or suggest a zinc-containing layered material having a relative zinc lability of greater than about 15%. The Office Action asserts that the disclosure of Wiese discloses that the zinc salt can be zinc oxide. The Office Action further asserts that from Wikipedia, zinc oxide is shown to clearly have a layered crystal structure. Therefore, since zinc oxide is a zinc layered material it would inherently have the same relative zinc lability of greater than about 15%, to greater than about 20% and to greater than about 25% and thus meet the limitations of the instant claims 1, 12 and 13. Applicants respectfully traverse this rejection.

Applicants respectfully maintain that zinc oxide is not a zinc containing layered material (i.e. ZLM). All chemical structures have repeating units occurring in three dimensions. Thus, it can appear to those looking at any crystal structure, that there are repeating layers. However, in conventional structural chemistry, the term “layered structures” refers to structures in which only very weak forces hold layers together. Information concerning layered structures is provided at <http://wwwold.ill.fr/dif/3D-crystals/layers.html>, a copy of which is enclosed herein.

The classical example would be diamond and graphite, both solid carbon materials differing only in the three-dimensional arrangement of the atoms. While the diamond crystal lattice has repeating “layers,” the bond strength is equally strong in all three dimensions. The resulting material is one of the strongest materials in existence. By contrast, graphite has strong bonds in only two dimensions (the “layers”), with only weak bonds between the layers, resulting in a very soft material. Information concerning these distinctions provided at <http://www.bris.ac.uk/Depts/Chemistry/MOTM/diamond/diamond.htm>, a copy of which is enclosed.

Likewise, zinc oxide has three-dimensionally symmetric bonding strength, without functionally identifiable layers; however, looking at the crystal lattice, there are repeating

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units in three dimensions and thus one could focus on two of the dimensions and consider them “layers”. In contrast, in zinc containing layered materials, such as basic zinc carbonate, there are well-defined layers of a given chemical composition that have strong intra-layer bonds but are only held together between layers by “gallery ions,” weak ionic bonds.

This is further supported by the Applicants specification on page 5, lines 5-10, which states zinc-containing layered structures are those with crystal growth primarily occurring in two dimensions. It is conventional to describe layer structures as not only those in which all the *atoms* are incorporated in well-defined layers, but also those in which there are *ions or molecules* between the layers, called gallery ions (A.F. Wells “Structural Inorganic Chemistry” Clarendon Press, 1975). Zinc-containing layered materials (ZLM’s) may have zinc incorporated in the layers and/or be components of the gallery ions. Therefore, the specification is disclosing layer structures as not only those in which all the *atoms* are incorporated in well-defined layers, but also those in which there are *ions or molecules* between the layers. This is the differentiation between crystal structure (atomic level) vs. crystal habit (shape that physically observable crystals take).

Applicants further refute the Office Action’s assertion that since zinc oxide is a zinc layered material it would inherently have the same relative zinc lability of greater than about 15%, to greater than about 20% and to greater than about 25% and thus meet the limitations of the instant claims 1, 12 and 13 based on data provided in the present application. Applicants direct attention to the specification at Page 30 line 33 to page 31 line 10, reproduced below:

-- Using this methodology, the below examples demonstrate a material (basic zinc carbonate) that has intrinsically high lability in an anionic surfactant system compared to one (ZnO) with low intrinsic lability.

	Relative Zinc Lability (%)	Relative Zinc Lability (%)	Lability Benefit
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	In Water	In Simple Surfactant System ¹	
Zinc Oxide	86.3	1.5	NO
Basic zinc carbonate	100	37	YES

¹Simple surfactant system: 6% sodium lauryl sulfate --

Clearly this data demonstrates, per column 2, that basic zinc carbonate, which is a zinc-containing layered material, in an anionic surfactant system, provides a lability benefit by achieving a relative zinc lability of 37%. In contrast, zinc oxide, in the same anionic surfactant system, has no lability benefit and only achieves a relative zinc lability of 1.5%. Therefore, zinc oxide does not inherently have the same relative zinc lability of greater than about 15%, to greater than about 20% and to greater than about 25% and thus does not meet the limitations of the instant claims.

In short, Applicants maintain that personal care compositions comprising a zinc-containing layered material having a relative zinc lability of greater than about 15%, as instantly claimed, is neither disclosed nor suggested by Wiese. When one of ordinary skill in the art compares the composition of Wiese to the instantly claimed invention, the compositions are not comprised of the exact same materials; namely Wiese does not teach or suggest a zinc-containing layered material, such as basic zinc-carbonate or others and would not inherently have the exact same properties as the currently claimed product, namely a zinc containing layered material having a relative zinc lability of greater than about 15%.

In light of the above remarks, it is requested that the Examiner reconsider and withdraw this rejection under 35 USC §102(b).

Rejection Under 35 USC §103(a) Over WO 01/00151 (hereinafter “Gavin et al.”) in view of EP 1145707 (hereinafter “Iwai et al.”) or WO 96/25913 (hereinafter “Bhat et al.”)

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Claims 1, 3, 4 and 7-25 have been rejected under 35 USC §103(a) as being unpatentable over WO 01/00151 (hereinafter “Gavin et al.”) in view of EP 1145707 (hereinafter “Iwai et al.”) or WO 96/25913 (hereinafter “Bhat et al.”).

The Office Action asserts that Gavin et al. do not expressly teach a composition comprising a zinc salt basic zinc carbonate. The Office Action further asserts that the deficiency in Gavin et al. is cured by the teachings of Iwai et al. or Bhat et al. It is further asserted that one of ordinary skill in the art would have been motivated to do this because Gavin et al. suggest adding zinc salts to the composition by not specifically basic zinc carbonate and Iwai et al. or Bhat et al. cure this deficiency by teaching that basic zinc carbonate is suitable for external compositions. Applicants respectfully traverse this rejection.

Iwai et al. discloses compositions for external use comprising 0.01-20 wt% of a zinc compound, such as basic zinc carbonate, 0.01-20 wt% of a thiol compound and anionic surfactant. The Office Action has asserted that the basic zinc carbonate taught by Iwai et al. would have the same level of zinc lability as instantly claimed. The Office Action further asserts that one of ordinary skill in the art would have been motivated to combine the teachings of Iwai et al. with Gavin et al. because Iwai et al. suggest the composition is useful for external use but not for those methods instantly claimed and Gavin et al. cure this deficiency by providing the teaching on the types of methods such a composition is useful for.

However, Applicants note that Gavin et al. discloses topical compositions for the treatment of microbial infections on the skin or scalp. Specifically, Gavin et al. requires an anti-microbial active selected from the group consisting of polyvalent metal salts of pyrithione and Iwai et al. requires the presence of a thiol, which is described in Iwai et al. at [0018} as being considered that a thiol compound having excellent antioxidative action and containing an SH group in the molecule can serve as an ingredient for preventing skin damage caused by solar UV rays. Therefore, Applicants maintain one of skill in the art would not be motivated to look to the disclosure of Iwai et al. which is based on a thiol compound and

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combine with the zinc pyrithione teachings by Gavin et al. and arrive at the present invention. Further, one of skill in the art would not be motivated to selectively pull out the basic zinc carbonate in Iwai et al., from the long list of zinc compounds, which are all clearly combined with a thiol and have any reasonable expectation of success that such a compound should be combined with the zinc pyrithione as taught by Gavin et al.

Applicants respectfully direct attention to the Iwai et al. disclosure on page 4, lines 23-26, wherein examples of zinc compounds include basic zinc carbonate and zinc pyrithione. Further, Examples 24A and 25A comprise zinc pyrithione. However, there is nothing exemplified in Iwai et al. that comprises the combination of basic zinc carbonate and zinc pyrithione or nothing in Iwai et al. that would specifically motivate one of skill in the art combine basic zinc carbonate and zinc pyrithione.

Further, Gavin et al. in view of Iwai et al. fails to teach or suggest wherein the ratio of a surfactant to zinc-containing layered material is greater than or equal to 2 to 1, as required in the present invention. Therefore, all of the claim limitations of the present invention are not taught or suggested by Gavin et al. in view of Iwai et al.

In summary, it is submitted that the combination of Gavin et al. in view of Iwai et al. fails to render the present claims unpatentable under 35 U.S.C. §103. A person skilled in the art would have no rationale or motivation to combine the teachings of Gavin et al. with Iwai et al., as one of skill in the art would not be motivated to add basic zinc carbonate as disclosed in Iwai et al. to the composition of Gavin et al.

Gavin et al discloses topical compositions for the treatment of microbial infections on the skin or scalp which include a polyvalent metal salt of pyrithione and include a metal ion source. Bhat et al. discloses the use of monophasic zinc hydroxycarbonate as antimicrobial agent in personal care products, particularly in such products which also contain a surfactant such as soap or a synthetic detergent.

The Office Action further has asserted Gavin et al. does not expressly teach a composition wherein the zinc salt is a zinc layered material, such as basic zinc carbonate.

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The Office Action further asserts that it would have been obvious to one of ordinary skill in the art to add basic zinc carbonate, as suggested by Bhat et al., to the composition of Gavin et al. and produce the instant invention. It is the Office Action's position that the basic zinc carbonate taught by Bhat et al. would have the same level of zinc lability as the present invention.

However, Applicant submits that the references cited fail to establish a *prima facie* case of obviousness. Specifically, Gavin et al. in view of Bhat et al. fails to teach or suggest all the claim limitations of the present invention. Gavin et al. in view of Bhat et al. fails to teach or suggest wherein wherein the ratio of surfactant to zinc-containing layered material is greater than or equal to 2 to 1. The Examiner has asserted the combination of Gavin et al. with Bhat's zinc hydroxycarbonate containing personal care product formulation would meet the zinc lability claim features.

However, as demonstrated in the table on page 31 of the present specification and the examples, the present invention has achieved efficacy with the technical rationale of a low level of basic zinc carbonate to high level of surfactant ratio. In contrast, if one of skill in the art were to look to Bhat et al., Bhat et al. exemplifies in Example 4 (a toothpaste) the exact opposite ratio of the present invention, a higher ratio of zinc hydroxycarbonate to surfactant ratio as compared to the present invention. Specifically, Bhat et al. teaches a ratio for a surfactant to zinc hydroxycarbonate of 2 to 3. This would clearly not lead one of skill in the art to the present invention ratio of surfactant to zinc-containing layered material greater than or equal to 2 to 1. As disclosed in the specification and presently amended claims, the present invention has found the components and ratios that result in the specified zinc lability. Gavin et al. in view of Bhat et al. does not provide the combination of the components and ratios that would lead one of skill in the art to the specified zinc lability. Further, one of skill the art would not be motivated to combine the teachings of Bhat et al. with Gavin et. al, as Bhat et al. is directed to a higher ratio of zinc component i.e. zinc hydroxycarbonate to surfactant, when compared to Gavin et al. which teaches the presence of higher ratio of surfactants to zinc components.

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Applicants further submit that one of skill in the art would not be *motivated* to combine the teachings of Bhat et al. with Gavin et al., as Bhat et al. is directed to a higher ratio of zinc component i.e. zinc hydroxycarbonate to surfactant, when compared to Gavin et al. which teaches the presence of higher ratio of surfactants to zinc components. If one of skill in the art were to combine the teaching of Gavin et al. with Bhat et al., there is no motivation to select the present invention's requirement of a ratio of surfactant to zinc-containing layered material greater than or equal to 2 to 1, especially in view that Gavin et al. does not disclose zinc containing layered materials. If one of skill in the art were looking to the Bhat et al. disclosure, Bhat et al. is directed to a higher ratio of zinc component i.e. zinc hydroxycarbonate to surfactant. And there is no rationale or motivation to combine with Gavin et al. which does not disclose zinc containing layered materials. As Applicants have previously submitted, the mere mention of many other zinc salts in Gavin, et al. is not anticipatory or suggestive of a zinc containing layered material as described and claimed herein.

Therefore, Applicants find that Gavin et al. in view of either Iwai et al. or Bhat et al. does not teach or suggest compositions having all of the claim limitations of the present invention, as defined in the present invention, and therefore fails to establish a *prima facie* case of obviousness.

Double Patenting

1) Claims 1, 3, 4, 7-17 and 23-25 have been provisionally rejected on the ground of nonstatutory obvious-type double patenting over claims 1, 8, 9, 11, 12, 14-17, 21 and 23-25 of copending U.S. Application No. 10/803,126.

In response to the above mentioned rejections, Applicants are submitting herewith a Terminal Disclaimer. Applicants contend that the Terminal Disclaimer moots the double patenting rejection.

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2) Claims 1, 3, 4, 7-22 and 25 have been provisionally rejected on the ground of nonstatutory obvious-type double patenting over claims 1, 2, 8-12, 16-32 and 34-39 of copending Application No. 11/602,770.

Claim 1 of the Application 11/602,770 is directed to a composition comprising an effective amount of a particulate zinc material; an effective amount of a surfactant including a deterersive surfactant with an anionic functional group; an effective amount of a pyrithione or a polyvalent metal salt of a pyrithione; a dispersed gel network phase comprising: i) least about 0.05 % of one or more fatty amphiphiles, by weight of said shampoo composition; ii) at least about 0.01 % of one or more secondary surfactants, by weight of said shampoo composition; at least about 0.01 % of one or more secondary surfactants, by weight of said shampoo composition; and iii) water; and at least about 20 % of an aqueous carrier, by weight of said shampoo composition.

In contrast, the instant invention is directed to a composition comprising from about 0.001% to about 5 % of a zinc-containing layered material; from about 10 % to about 50% of a surfactant including a surfactant with an anionic functional group; from about 0.01% to about 5% of a pyrithione or a polyvalent metal salt of a pyrithione; wherein the zinc-containing layered material has a relative zinc lability of greater than about 15% and further wherein the ratio of surfactant to zinc-containing layered material is greater than or equal to 2 to 1.

The currently claimed invention is not directed to a composition containing a dispersed gel network phase comprising: i) least about 0.05 % of one or more fatty amphiphiles, by weight of said shampoo composition; ii) at least about 0.01 % of one or more secondary surfactants, by weight of said shampoo composition; at least about 0.01 % of one or more secondary surfactants, by weight of said shampoo composition; and iii) water. Further, the '770 application is not directed to or requires a relative zinc lability of greater than about 15% for a zinc-containing layered material. Yet further, the '770 does not require or teach the amount of zinc layered material or a ratio of surfactant to zinc layered material of greater than or equal to 2:1. These 2 claim sets are patentably distinct and each of the

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specification and data demonstrate that the determination of gel network phase in the '770 application or relative zinc lability in the currently claimed invention is not a matter of routine optimization. A gel network phase, relative zinc lability and ratio of surfactant to zinc containing layered material of 2:1 are clearly distinct components.

Therefore, Applicants respectfully request reconsideration and removal of this double patenting rejection.

3) Claims 1, 3, 4, 7-22 have been provisionally rejected on the ground of nonstatutory obvious-type double patenting over claims 1, 2, 9, 13-30, 35 and 17 of copending Application No. 11/890,684.

Claim 1 of the Application 11/890,684 is directed to a composition comprising an effective amount of a particulate zinc material; an effective amount of a surfactant including a surfactant with an anionic functional group; an effective amount of a pyrithione or a polyvalent metal salt of a pyrithione; from about 0.025% to about 5% by weight of a water soluble or dispersible, cationic, non-crosslinked, conditioning homopolymer having a cationic charge density of from about 2 meq/gm to about 10 meq/gm; and from about 20% to about 95% of an aqueous carrier, by weight of said composition.

In contrast, the instant invention is directed to a composition comprising from about 0.001% to about 5 % of a zinc-containing layered material; from about 10 % to about 50% of a surfactant including a surfactant with an anionic functional group; from about 0.01% to about 5% of a pyrithione or a polyvalent metal salt of a pyrithione; wherein the zinc-containing layered material has a relative zinc lability of greater than about 15% and further wherein the ratio of surfactant to zinc-containing layered material is greater than or equal to 2 to 1.

The currently claimed invention is not directed to a composition containing from about 0.025% to about 5% by weight of a water soluble or dispersible, cationic, non-crosslinked, conditioning homopolymer having a cationic charge density of from about 2 meq/gm to about 10 meq/gm. Further, the '684 application is not directed to or requires a

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relative zinc lability of greater than about 15% for a zinc-containing layered material. Yet further, the '684 application does not require the amount of zinc layered material or a ratio of surfactant to zinc layered material of greater than or equal to 2:1. These 2 claim sets are patentably distinct and each of the specification and data demonstrate that the determination of liquid crystal phase in the '684 application or the ratio of surfactant to zinc layered material and relative zinc lability as required in the currently claimed invention are not a matter of routine optimization. In the '684 application, the surprising discovery that compositions combining certain water soluble or dispersible, cationic, non crosslinked, deposition polymers in combination with surfactants form microscopically-phase separate lyotropic liquid crystals suspended in an aqueous surfactant phase is clearly patentably distinct. In use, the dispersed, concentrated polymer lyotropic liquid crystal phase provides improved hair and skin conditioning.

Therefore, Applicants respectfully request reconsideration and removal of this double patenting rejection.

4) Claims 1, 3, 4, 7-25 have been provisionally rejected on the ground of nonstatutory obvious-type double patenting over claims 1-5, 11-27 and 33-46 of copending Application No. 11/899,106.

Claim 1 of the Application 11/899,106 is directed to a composition comprising an effective amount of a zinc containing material having an aqueous solubility within the composition of less than about 25% by weight at 25°C; from about 5% to about 50% of a surfactant; and from about 40% to about 95% water; wherein the pH of the composition is greater than about 7.

In contrast, the instant invention is directed to a composition comprising from about 0.001% to about 5 % of a zinc-containing layered material; from about 10 % to about 50% of a surfactant including a surfactant with an anionic functional group; from about 0.01% to about 5% of a pyrithione or a polyvalent metal salt of a pyrithione; wherein the zinc-containing layered material has a relative zinc lability of greater than about 15% and further

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wherein the ratio of surfactant to zinc-containing layered material is greater than or equal to 2 to 1.

The currently claimed invention is not directed to a composition comprising a zinc containing material having an aqueous solubility within the composition of less than about 25% by weight at 25°C. In contrast, the currently claimed invention requires the limitation of a zinc-containing *layered* material. Further, the '106 application claims require that the zinc containing material have an aqueous solubility within the composition of less than about 25% by weight at 25°C. Further, the '106 application does not require a relative zinc lability of greater than about 15% for a zinc-containing layered material, as required in the currently claimed invention. Yet further, the '106 application does not require the amount of zinc containing *layered* material or a ratio of surfactant to zinc layered material of greater than or equal to 2:1. These two claim sets are patentably distinct.

Therefore, Applicants respectfully request reconsideration and removal of this double patenting rejection.

5) Claims 1, 3, 4, 7, 8, 12, 13 and 15-17 have been provisionally rejected on the ground of nonstatutory obvious-type double patenting over claims 1 and 4-7 of copending Application No. 12/029,150.

Claim 1 of the Application 12/029,150 is directed to a personal care method, comprising the step of topically applying a personal care composition to areas of the body other than the scalp and hair growing therefrom, the personal care composition comprising zinc-containing layered material; and a surfactant with an anionic functional group; wherein the zinc-containing layered material has a relative zinc lability of greater than about 15%.

In contrast, the instant invention is directed to a composition comprising from about 0.001% to about 5 % of a zinc-containing layered material; from about 10 % to about 50% of a surfactant including a surfactant with an anionic functional group; from about 0.01% to about 5% of a pyrithione or a polyvalent metal salt of a pyrithione; wherein the zinc-containing layered material has a relative zinc lability of greater than about 15% and further

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wherein the ratio of surfactant to zinc-containing layered material is greater than or equal to 2 to 1.

The currently claimed invention is not directed to a personal care *method*, comprising the step of topically applying a personal care composition to areas of the body *other than the scalp and hair growing therefrom*. In contrast, the currently claimed invention, namely Claims 1, 3, 4, 7, 8, 12, 13 and 15-17 are directed to a personal care composition. Further, the '150 application does not require the amount of zinc containing layered material or a ratio of surfactant to zinc layered material of greater than or equal to 2:1. Yet further, the '150 application does not require a pyrithione or a polyvalent metal salt of a pyrithione, as required in the currently claimed invention. Therefore, these two claim sets are patentably distinct.

Applicants respectfully request reconsideration and removal of this double patenting rejection.

Conclusion

In light of the above remarks, it is requested that the Examiner reconsider and withdraw the rejection under 112, 102(b) and 103(a). Early and favorable action in the case is respectfully requested.

This response represents an earnest effort to place the application in proper form and to distinguish the invention as now claimed from the applied references. In view of the foregoing, reconsideration of this application, entry of the amendments presented herein, and allowance of Claims 1, 3 and 7-27 is respectfully requested.

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Respectfully submitted,

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